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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/385,834	08/30/1999	JEFFREY L. C. WRIGHT	76891	9704

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EXAMINER

QAZI, SABIHA NAJM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/385,834	Applicant(s) WRIGHT, JEFFREY L. C.	
	Examiner Sabiha Qazi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-11,34,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-11,34,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Invention: Claims are drawn to a nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject, said nutritional supplement comprising: a sterol ester of an omega-3 fatty acid, wherein said omega-3 fatty acid is selected from the group consisting of EPA, DHA, and SA.

Continued Prosecution Application

The request filed on February 17, 2004 for a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/2004 has been entered.

Claims 1, 5-11, 34, 39 and 40 are pending. No claim is allowed. Due to an inadvertent error, the previous action mailed on June 29, 2004 is withdrawn. Examiner apologizes for any inconvenience caused by this error.

ISSUES

Declaration Pursuant to 37 CFR 1.131

The Applicant argues that HIGGINS III (US Patent No. 6147236) is not prior art because of the Declaration filed by the Applicant for priority. Examiner respectfully disagrees.

In the Declaration filed by the Applicant on May 5, 2003, the Applicant states, "I, Jeffrey L.C. Wright, hereby declare that: 2) Prior to December 15, 1998, I conceived the idea..."

The declaration filed on May 5, 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Higgins reference, US Patent 6,147,236.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Higgins reference, US Patent 6,147,236. See MPEP 715.07

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Higgins's reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Higgins's reference, US Patent 6,147,236 to either a constructive reduction to practice or an actual reduction to practice.

See MPEP 2138.04 [R-1] through 2138.06

"Conception"

Conception has been defined as "the complete performance of the mental part of the inventive act" and it is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice...." *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930). CONCEPTION MUST BE DONE IN THE MIND OF THE INVENTOR The inventor must form a definite and permanent idea of the complete and operable invention to establish conception. *Bosies v.*

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Benedict, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994) (Testimony by a noninventor as to the meaning of a variable of a generic compound described in an inventor's notebook was insufficient as a matter of law to establish the meaning of the variable because the testimony was not probative of what the inventors conceived.).

ARGUMENTS

Concerning 35 USC 103

HIGGINS III and HIGASHIDATE et al.

Claims 5-11, 34, 39, and 40 stand rejected under 35 USC 103 as being unpatentable over HIGGINS III (US Patent No. 6147326) and HIGASHIDATE et al. (Journal of Chromatography, (1990) 515:295-303).

The argument that HIGGINS III is not prior art

Examiner respectfully disagrees. For detailed reasons, please see "Issues" above where conception and reduction of practice has been discussed.

The argument that HIGASHIDATE et al. does not cure the defects in HIGGINS III

Applicant argues that HIGASHIDATE et al. does not by itself render obvious the instant claims. Examiner couldn't agree more. But Examiner maintains that HIGGINS III is prior art, and in combination with HIGASHIDATE et al., it renders the instant claims *prima facie* obvious.

The argument that the Applicant's Declaration under 37 CFR 1.131 antedates HIGGINS

III

Applicant submits, "...because HIGGINS III does not claim the subject matter of any of instant claims 1, 5-11, 34, or 39, priority of invention is not an issue. Hence, the date on which the invention claimed in HIGGINS III reference is not relevant."

The priority of invention is an issue because HIGGINS III does claim the subject matter of the instant claim which is obvious. Examiner would like to direct the Applicant's attention to claims 1 and 16-22, which are drawn to the compounds and method of producing serum cholesterol in humans.

Applicant's Declaration under 37 CFR 1.131

The Declaration under 37 CFR 1.131 is insufficient to overcome the HIGGINS III rejection for the reasons cited above.

A 37 CFR 1.131 affidavit is ineffective to overcome a United States patent or patent application publication, not only where there is a verbatim correspondence between claims of the application and of the patent, but also where there is no patentable distinction between the respective claims. In re Clark, 457 F.2d 1004, 173 USPQ 359 (CCPA 1972); In re Hidy, 303 F.2d 954, 133 USPQ 650 (CCPA 1962); In re Teague, 254 F.2d 145, 117 USPQ 284 (CCPA 1958); In re Ward, 236 F.2d 428, 111 USPQ 101 (CCPA 1956); In re Wagenhorst, 62 F.2d 831, 16 USPQ 126 (CCPA 1933).

MPEP 2308.01 Patent Has Filing Date Earlier Than Application

Applicant's attention is drawn to MPEP 2308.1, which is quoted below.

"When an applicant attempts to provoke an interference with a patent, the examiner must determine the effective filing dates of the application and of the patent; only the patent's

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effective United States filing date will be considered. Any claim of foreign priority by the patentee under 35 U.S.C. 119(a) will not be taken into account when determining whether or not an interference should be declared, in order to be consistent with the holding in *In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966), that the effective date of a United States patent as a reference is not affected by the foreign filing date to which the patentee is entitled under 35 U.S.C. 119(a). If the patentee is determined to be entitled to the benefit of a prior United States application as to claimed subject matter involved in the interference, that application must be listed on the PTO-850 form (see MPEP § 2309.02).

If the effective filing date of the application is 3 months or less after the effective filing date of the patent, the applicant must submit a statement alleging that there is a basis upon which the applicant is entitled to a judgment relative to the patentee. 37 CFR 1.608(a). The statement may be made by persons other than the applicant. See MPEP § 715.04.

If the effective filing date of the application is more than 3 months after the effective filing date of the patent, 37 CFR 1.608(b) requires that the applicant must file (A) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is prima facie entitled to a judgment relative to the patentee, and (B) an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment.

If an applicant is claiming the same invention as a patent which has an earlier effective United States filing date but there is not a statutory bar against the application, and the applicant has not submitted the items required by 37 CFR 1.608(a) or (b), as appropriate, the application should be rejected under 35 U.S.C. 102(e)/103. A statement should be included in the rejection

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that the patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note, however, 35 U.S.C. 135(b) and MPEP § 2307. The applicant should also be advised that an affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

If the applicant does not agree he or she is claiming the same invention as the patent, and files an affidavit under 37 CFR 1.131, the rejection should be repeated and made final. The rejection should specify what the count or counts of the interference between the application and the patent would be. If the applicant still disagrees with the examiner, the rejection may be appealed to the Board of Patent Appeals and Interferences, and the question of whether the application and the reference patent are claiming the same invention may be argued on appeal, inasmuch as the 37 CFR 1.131 affidavit cannot be considered unless the applicant is found to be claiming an invention which is patentably distinct from that claimed in the patent. See *In re Clark*, 457 F.2d 1004, 173 USPQ 359 (CCPA 1972) and *In re Hidy*, 303 F.2d 954, 133 USPQ 650 (CCPA 1962)."

Examiner suggests that Applicants also see MPEP 2306-2308.

Applicant's Declaration under 37 CFR 1.132

Declaration filed by H. Stephen Ewart on July 10, 2002 was fully considered but was not persuasive. Because the reaction of a sterol with fatty acids is known as cited in prior art of record. Furthermore prior art teaches that esters are better than separate mixtures of a sterol and fatty acids. No unexpected results are seen.

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The arguments that Mitchell process for preparation was repeated and the mixture was stirred for 2 hours no product was formed. Examiner respectfully disagrees and would refer to example 1 of Mitchell's reference when reaction was done in example 1 for 3 hours, Example 3 for 2 hours, example 4 for 1 hour and example 13 for 1 and half hours. One skilled in the art would know at the time of invention that depending on different fatty acid compositions and amounts of reactants when monitoring the reaction forms the product. For the same reasons some reactions for forming the ester may take more time than the other as has been exemplified by the US '717 (Mitchell).

In order to advance the prosecution the references cited in the rejection teach and/or disclose the formation of ester from a sterol and fatty acid.

Applicant's submissions concerning the combined teachings of MITCHELL, MISHKEL et al., and KAMAREI et al.

Previous 103 rejection over MITCHELL is maintained.

The Applicant states on Page 17 of the Remarks filed on February 17, 2004: "However, these are merely passing statements in the background of the invention section of KAMAREI et al. and are not concerned with KAMAREI et al.'s invention concerning angiogenesis."

Examiner respectfully disagrees. Every line in a published United States Patent is considered to be a reference, and therefore, prior art. Nothing in a patent is a "passing by statement". The claims are drawn to a method for provoking or enhancing angiogenesis, but the reference TEACHES that there is much evidence that a diet rich omega-3 fatty acid has beneficial effects in humans, including a reduction in plasma cholesterol and triglyceride levels.

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Examiner would like to direct the Applicant's attention to lines 63-68 in col. 2 and lines 1-5 in col. 3, which states: "RUBIN, US Pat. No. 4526902...the teaching that mixtures of EPA and DHA/linoleic acid derivatives need not be administered as pharmaceuticals, but that they can also be administered in food form, such as cooking oil or margarine.

See MPEP 2123, "Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments" PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.")

The rejection over MISHKEL et al. and KAMAREI et al. is withdrawn. The Examiner still believes that MISHKEL et al. and KAMAREI et al. are valid references, but in order to advance the prosecution of this application, Examiner has decided to withdraw the rejections over MISHKEL et al. and KAMAREI et al.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 5-11, 34, 39, and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over HIGGINS III (US Patent No. 6147236) and HIGASHIDATE et al. (J. of Chromatography, 515 (1990), 295-303). These references teach sterol esters and methyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which embrace instantly, claimed invention. See the entire documents especially lines 9-67, col. 2; cols. 3 and 4; lines 1-20, col. 5 in HIGGINS III; see abstract and first Para on page 295, Table 1 and last two paragraphs on page 302 in HIGASHIDATE et al. reference.

Lines 9-10 in col. 4 of HIGGINS III states, **"...both DHA and CLA have been reported to possess cholesterol-lowering activities."** Lines 11-15 go on to state, "Therefore, a compound which contains **the combination of both the stanol or sterol with a pendent ester functionality** which when hydrolyzed **provides another cholesterol-limiting agent would be highly beneficial."**

Instant claims differ from the reference in claiming nutritional supplement of specific sterol esters prepared by unsaturated fatty acid esters selected from EPA, DHA and Stearidonic acid (SA) whereas prior art HIGGINS III teaches sterol esters with unsaturated fatty acids, examples given is same as one of the instantly claimed sterol ester i.e. sterol with DHA, sitosterol docosahexaenoate and sitostanol docosahexaenoate, see lines 13 and 14 in col. 5. HIGASHIDATE et al. teaches DHA and EPA from fish oils and prevent diseases such as

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arteriosclerosis and myocardial infarction by lowering the concentration of lipids and cholesterol in blood. It discloses that fish oil is a rich source of such fatty acids. Stearidonic acid (SA) is also found in fish oil.

It would have obvious to one skill in the art to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent. Since HIGGINS III teaches such sterol esters and HIGASHIDATE et al. teaches that fish oil contains omega-3 fatty acids (a class of PUFA) which includes docosahexaenoic acid (DHA) and eicosahexaenoic acid (EPA), one would find ample motivation to prepare sterol esters with unsaturated fatty acids from active compounds present in fish oil (known to be used as nutritional supplement to lower the cholesterol and triglyceride levels) or using unsaturated fatty acids from any other source for use as nutritional supplement.

2. Claim(s) 1, 5-11, 34 and 39 are rejected under 35 U.S.C. 103 as being unpatentable over the teachings of MITCHELL (US Patent No. 4588717). See the entire documents.

MITCHELL teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations, a composition of the phytosterols, such as sitosterol, stigmasterol, taraxasterol etc. reacted with polyunsaturated fatty acids such as linoleic acid, (18-carbons, two double bonds), linolenic acid (18-carbons, 3-double bonds), arachidonic acid (20-carbons, two double bonds). Fatty acid may have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given

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fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Instant claims differ from the reference in claiming nutritional supplement of phytosterol ester with specific fatty acids i.e. docosahexaenoic acid, stearidonic acid and eicosahexaenoic acid where MITCHELL teaches phytosterol ester with fatty acids especially containing poly unsaturated fatty acid approximately 2-22 carbon atoms. See examples 51-75 in col. 6, equation 2 in cols 15, 16, 17 and 18.

It would have been obvious to one skilled in the art to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent. There has been ample motivation provided by the prior art to prepare the instant invention.

Since HIGGINS III teaches food grade sitosterol docosahexaenoate and sitostanol docosahexaenoate and other references cited above teach DHA, EPA and fish oil containing n-3 PUFA i.e. eicosapentaenoic acid (EPA) and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity, instant invention is considered obvious for the reasons cited above.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

NEW REJECTIONS

Double Patenting

Claims 1, 5-11, 34, 39 and 40 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-13 of copending Application No. 10/070181. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Instant claims are drawn to a nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject, said nutritional supplement comprising: a sterol ester of an omega-3 fatty acid, wherein said omega-3 fatty acid is selected from the group consisting of EPA, DHA, and SA. The claims of copending Application 10/070181 are drawn to a nutritional supplement comprising an ester formed between a sterol and an omega-3 fatty acid for lowering cholesterol and triglyceride levels in the bloodstream of a subject.

Instant claims differ from the claims of '181 in being the selection of the subject matter of the copending application. Because the nutritional supplement of a sterol and an omega-3 fatty acid overlaps with the presently claimed invention containing the sterols with specific omega-3 fatty acids that is EPA, DHA, and SA, it is considered *prima facie* obvious.

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It would have been obvious to one skilled in the art at the time of invention to prepare the specific nutritional supplement of a sterol and an omega-3 fatty acid by selecting these three because they are known to be the most effective at lowering cholesterol and triglyceride levels.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by HORROBIN (US Patent No. 5604216). See compound 1C in Example 3 (Cholesteryl eicosapentaenoate), claim 1 (which is the cholesteryl fatty acid ester of DHA, EPA, and SA), and claim

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for

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patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 8, 11, 34, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by HIGGINS III (US Patent No. 6147236). See lines 1-15 in col. 5, Example 9, and claim 20.

Even though claims are not drawn to the method of use, Examiner is making an enablement rejection in order to advance the prosecution because the Applicants have argued the lowering of cholesterol and triglyceride levels throughout the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-11, 34, 39, and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the phytosterol ester preparation with omega-3 fatty acids selected from DHA, EPA, and SA does not reasonably provide enablement for the

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nutritional supplement for lowering cholesterol and glyceride levels in the bloodstream in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention: The claims are drawn to a nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject, said nutritional supplement comprising a sterol ester of an omega-3 fatty acid selected from the group consisting of EPA, DHA, and SA.

(2) The breadth of the claims: The claims are broad; they are drawn to sterol esters, which includes phytosterols and any other sterols, such as cholesterol.

(3) The amount of direction or guidance presented: There is no guidance in the disclosure on how to use the invention successfully for lowering cholesterol and triglyceride levels.

In *re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (*Fields v. Conover*, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (*In re Colianni*, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971)).

(4) The presence or absence of working examples: There are no working examples and/or data to support the claimed invention. The disclosure does not contain any working examples. There is only one example on page 12 of the Specification, which is the synthesis of stigma sterol and omega-3 fatty acid esters.

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A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(5) The quantity of experimentation necessary: Since there are no working examples, no data, and no guidance presented in the disclosure, one skilled in the art at the time of invention would have to go through undue experimentation to make and use the presently claimed invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-11, 34, 39 and 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are no steps in claims 1. Claims do not recite specific steps for lowering of cholesterol and triglyceride in the blood stream of a subject. See MPEP 2173.05(q).

Therefore, the claims are drawn to the compounds and not the method of use.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-11, 34, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over HORROBIN (US Patent No. 5604216) and MIETTINEN et al. (US Patent No. 5502045). These references teach the use of a stanol fatty acid ester for reducing cholesterol and triglyceride levels, which embraces the presently claimed invention.

HORROBIN teaches the cholesterol fatty acid esters where the fatty acid esters are EPA, DHA, and SA useful for lowering cholesterol. See the entire document, especially the abstract, Tale 1 in col. 1, lines 19-65 in col. 2, compounds 1 and 2 in col. 4, lines 11-39 in col. 4, all examples (especially example 3), and claim 1.

MIETTINEN et al. teaches the preparation of a stanol fatty acid ester for reducing serum cholesterol levels. It also teaches that a beta-sitostanol fatty acid ester mixture decreased both total cholesterol and LDL cholesterol more effectively than did free and beta-sitostanol. See the entire document, especially lines 43-67 in col. 3, lines 1-7 in col. 4, lines 54-60 in col. 4, examples, and claims.

It would have been obvious to one skilled in the art at the time of invention to prepare a nutritional supplement for lowering cholesterol and triglyceride levels in the blood stream of a subject, said nutritional supplement comprising: a sterol ester of an omega-3 fatty acid, wherein said omega-3 fatty acid is selected from the group consisting of EPA, DHA, and SA because the

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prior art teaches the use of a stanol fatty acid ester for reducing cholesterol and triglyceride levels, which embraces the presently claimed invention.

One skilled in the art would have been motivated to prepare the presently claimed invention because the prior art teaches that beta-sitostanol fatty acid ester mixture decreased both total cholesterol and LDL cholesterol more effectively than did free and beta-sitostanol.

Instant invention is different from the prior art in claiming a broader, more generic scope.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The Examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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SABIHA QAZI, PH.D
PRIMARY EXAMINER

Friday, September 17, 2004